Cepheid
A better way.

Xpert® Xpress CoV-2/Flu/RSV *plus*



Actionable rapid respiratory results to meet the challenges of co-circulating respiratory viruses

The Need

Detection and differentiation of Flu A, Flu B, RSV and SARS-CoV-2, which all present with similar symptoms

- Fast results for symptomatic patients to facilitate early diagnosis, effective triage, and patient management.[1]
- Ensuring the accuracy of test performance despite new SARS-CoV-2 variants[2] and influenza A mutations.[3]
- Multiplexing ability for the most prevalent and actionable pathogens (SARS-CoV-2, influenza A, influenza B, RSV) to simplify the diagnosis process.
- Fast, multiplex results that provide the right result first time, reducing costs associated with reflex and/or confirmatory testing.[4]

The Solution

The Xpert **Xpress** CoV-2/Flu/RSV ***plus*** test is a multiplexed real-time PCR test intended for the simultaneous *in-vitro* qualitative detection and differentiation of RNA from SARS-CoV-2, influenza A, influenza B, and/or RSV in nasopharyngeal swab or anterior nasal swab specimens collected from individuals with signs and/or symptoms of respiratory viral infection.

The Xpert **Xpress** CoV-2/Flu/RSV ***plus*** test:

- Provides fast and accurate results in **as early as 25 minutes**[#] for SARS-CoV-2 or Flu only results.
- Utilizes a **multi-gene target approach** for the detection of SARS-CoV-2 and influenza providing target redundancy to **mitigate the potential impact of genetic shift and drift** on strain detection.
- **Detects** SARS-CoV-2, influenza A, influenza B, and/or RSV simultaneously.

The Impact

- Xpert **Xpress** CoV-2/Flu/RSV ***plus*** allows for accurate and fast results, optimizing diagnostic efficiency and improving the provision of appropriate treatment[5]
- Testing with Xpert **Xpress** CoV-2/Flu/RSV ***plus*** may result in significant cost-savings compared to antigen and send-out PCR testing strategies and may result in fewer hospitalizations, ICU admissions, mechanical ventilations, and deaths[6]
- Gives the right result the first time, reducing the need for reflex and/or confirmatory testing[7]

* With Early Assay Termination (EAT) for positive results.

1 Strategic preparedness and response plan: April '23 –'25. https://iris.who.int/bitstream/handle/10665/372712/WHO-WHE-SPP-2023.2-eng.pdf?sequence=1
2 https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests
3 Jørgensen, R. L. et al. Emergence of circulating influenza A H3N2 viruses with genetic drift in the matrix gene: be alert of false-negative test results. APMIS 130, 612–617 (2022).
4 Chase, J. HSD13 Missed Opportunities for Respiratory Disease Diagnosis in the United States During Endemic Spread of SARS-CoV-2. Value in Health, Volume 27, Issue 6, S22
5 Davies S et al. A cost-consequence analysis of the Xpert® Xpress CoV 2/Flu/RSV plus test strategy for the diagnosis of influenza-like illness. Association for Molecular Pathology 2023 Annual Meeting Abstracts. J Mol Diagn 2023, p 64 Abstract 039
6 Davies, E. et al (2023) A Cost-Consequence Analysis of Xpert Xpress CoV-2/Flu/RSV Plus for the Diagnosis of Viral Respiratory Infections from a US Health Plan Perspective. J Mol Diagn, 25(11) (S1-S186): S64. https://www.jmdjournal.org/article/S1525-1578%2823%2900249-0/pdf
7 K. Stockl, et al. (2023). Use of Antigen and Molecular Testing for Coronavirus 2019 (SARS-CoV-2) among Patients with Influenza-Like Illness (ILI) in the Non-inpatient Setting. J Mol Diagn, 25(11) (S1-S186): S53. https://www.jmdjournal.org/article/S1525-1578%2823%2900249-0/pdf

Xpert® Xpress CoV-2/Flu/RSV *plus*

Product Reference Sheet — FDA Cleared Moderate Complexity and CLIA Waived

Test Reagent Kit	Xpert **Xpress** CoV-2/Flu/RSV ***plus***
Catalog Number	XPRS4PLEX-10
Technology	Real-time RT-PCR
Targets	**SARS-CoV-2** **RdRP:** RNA-dependent RNA polymerase gene **N2:** nucleocapsid gene **E:** envelope protein gene **Flu A** Matrix protein gene PB2 PA **Flu B** Matrix protein gene Non-structural protein **RSV** RSV A RSV B
Batch or On-Demand	On-Demand
Minimum Batch Size	1
Sample Types	**Specimen Collection:** Nasopharyngeal or anterior nasal swabs **Transport Media:** 3 mL of Universal/Viral Transport Media (UTM/VTM) and 2 mL eNAT
Sample Extraction	Automated/Integrated
Precision Pipetting	Not required
TAT	Approximately 36 minutes. 25 minutes with early assay termination for positive results on SARS-CoV-2 and Flu.[#]
Hands-on Time	< 1 minute
Controls: Process	Sample Processing Control
Controls: Probe Function/Detection	Probe Check Control

	MODERATE		WAIVED	
	Nasopharyngeal specimens		Nasopharyngeal specimens	
	PPA	NPA	PPA	NPA
SARS-CoV-2	97.1% (95.1%–98.2%)	98.2% (97.5%–98.7%)	98.7% (96.6%–99.5%)	98.5% (97.7%–99.0%)
Flu A	99.0% (96.3%–99.7%)	99.1% (98.7%–99.4%)	99.1% (96.6%–99.7%)	98.5% (97.9%–99.0%)
Flu B	96.6% (88.5%–99.1%)	100.0% (99.9%–100.0%)	96.6% (88.5%–99.1%)	99.9% (99.7%–100.0%)
RSV	98.6% (92.5%–99.8%)	100.0% (99.9%–100.0%)	97.8% (92.4%–99.4%)	99.9% (99.7%–100.0%)
	Nasal specimens		Nasal specimens	
	PPA	NPA	PPA	NPA
SARS-CoV-2	98.2% (96.6%–99.1%)	98.8% (98.3%–99.2%)	98.4% (96.2%–99.3%)	99.3% (98.7%–99.6%)
Flu A	98.0% (94.9%–99.2%)	99.3% (99.00%–99.6%)	97.6% (94.6%–99.0%)	98.9% (98.3%–99.2%)
Flu B	100.0% (89.8%–100.0%)	99.9% (99.7%–100.0%)	100.0% (89.9%–100.0%)	99.9% (99.6%–100.0%)
RSV	95.8% (88.5%–98.6%)	100.0% (99.9%–100.0%)	97.0% (91.5%–99.0%)	99.9% (99.6%–100.0%)

Sample Storage	15–30 °C for up to 48 hours until testing is performed in viral transport medium or eNAT 2–8 °C for up to 7 days until testing is performed in viral transport medium or up to six days in eNAT -20 °C or -80 °C and undergo 1 freeze/thaw cycle until testing is performed in viral transport medium or eNAT
Kit Storage	2–28 °C
Commercial Controls	Refer to Xpert **Xpress** CoV-2/Flu/RSV ***plus*** Package Insert or contact Cepheid Technical Support

* With Early Assay Termination (EAT) for positive results.

Refer to Xpert **Xpress** CoV-2/Flu/RSV ***plus*** package insert 302-8057 and 302-8058 current version for complete details.

US-IVD. For *In Vitro* Diagnostic Use in laboratories that are CLIA waived certified to perform moderate or high complexity tests.

CORPORATE HEADQUARTERS
904 Caribbean Drive
Sunnyvale, CA 94089 USA

TOLL FREE **+1.888.336.2743**
PHONE **+1.408.541.4191**
FAX **+1.408.541.4192**

www.**Cepheid**.com

© 2023–2025 Cepheid. 10073-03

danaher